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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,958	01/05/2001	Manfred Auer	4-30730B/D1	6787

1095 7590 05/06/2003

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/06/2003

11 J

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/754,958

Applicant(s)

Auer et al

Examiner

Maurie G. Baker

Art Unit

1639

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 2, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-16 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. The Response filed January 2, 2003 (Paper No. 10) is acknowledged. Claims 12-16 are pending and under examination.
2. The last communication from the examiner was a Notice of Non-Responsive Amendment stating that the previous response filed on September 9, 2002 canceling all claims drawn to the elected invention and presenting only claims drawn to a non-elected invention was deemed to be non-responsive (MPEP § 821.03). Applicant's arguments filed January 2, 2003 in response to this Notice were found partially persuasive. Thus, although applicant has not amended the claims, the case is examined on the merits.
3. However, the following is noted for the record. Applicant does seem to have changed the claimed invention, or, at the least, has rendered it more confusing than what was previously set forth (i.e. in previous claims 3-5). However, in the interest of compact prosecution, the examiner has examined newly filed claims 12-16 in this action.

Status of Rejections

4. Previously examined claims 3-5 have been cancelled. Thus rejections pertaining to these claims are moot. However, newly filed claims 12-16 are rejected below for similar reasons. Applicant's arguments are addressed following each rejection, as much

as they pertain to the new rejection over claims 12-16. Note that the new rejections are necessitated by applicant's amendments.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 12, 13, 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Applicant's claims are directed to compounds "comprising structures of the formulae II - III" where these formulae are defined as "A-B-D-C-D' - (Formula (II))" and "A-B-D- and -D'-C (Formula (III))". For claims 12, 13, 15 and 16, the following applies: (1) no specific linkage sites between each of the moieties are depicted whatsoever and (2) several portions of this molecule are set forth in only functional terms. For example, claim 12 recites that A is selected from various solid supports;

however, there is no information as to exactly how the compounds are to be attached to these supports. Moreover, the B portion of the claimed molecules is defined only as "a linker allowing cleavage of fluorescent conjugates of formula (II – III)". Applicant's claimed scope represents only an invitation to experiment regarding possible compounds of formula (II – III) and portions thereof that have the claimed functions.

The present application fails to describe sufficient examples of compounds of formula (II – III) that are within the scope of the presently claimed invention. The instant description discloses the preparation of only a very limited number of compounds of formula (II – III). The instant description also discloses only a limited number of examples of how the instant portions of the molecules (A, B, C, D and D') can be linked together to form such compounds.

With respect to adequate disclosure of the scope of the presently claimed generic applicant is referred to the discussion in *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175) regarding disclosure. For adequate disclosure, like enablement, requires *representative examples* which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that *applicant had possession of the full scope of the claimed invention*. See *In re Riat* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr* (CCPA 1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and *University of California v. Eli Lilly and*

Co cited above (for disclosure). The more unpredictable the art the greater the showing required (e.g. by "representative examples") for both enablement and adequate disclosure.

Therefore it is deemed that the disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Moreover, the claimed genus encompasses members which are yet to be prepared or envisioned. This further evidences that the structural features of the exemplified compounds do not constitute support for the claimed genus or a substantial portion thereof.

Response to Arguments

7. Applicant's arguments filed September 9, 2002 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

8. Applicant argues that the claims are adequately described and points to portions of the instant specification (Response, pages 6-7). The examiner's position is that the definitions in the specification for the terms discussed in the rejection are *very broad*. This is not adequate description of the compounds as claimed, especially with respect to the linkages between each of the components. Thus the claims could encompass an infinite number of variations. Note that "the essential goal of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ

470, 473 n.4 (CCPA 1977), cert. denied, 434 U.S. 1064 (1978). Another objective is to put the public in possession of what the applicant claims as the invention so that the public may ascertain if the patent applicant claims anything that is in common use, or already known. *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356 (1822).

9. The language of the specification should describe the claimed invention so that one skilled in the art can recognize what is claimed. A description of a compound in terms of its function fails to distinguish the compound from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175). Applicant argues that, for example, in moiety C “[p]ossible specific linkage sites are clearly defined”. The examiner disagrees as there is nothing in the claim that makes it clear what sites are the linkage sites.

10. Lastly, an objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). The examiner maintains because of the breadth of the claims and the unpredictability of the art, the above standard is not

met. Thus the above rejection of newly added claims 12, 13, 15 and 16 under 35 U.S.C. 112, first paragraph is made.

11. Claims 12, 13, 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds comprising *specific* A, B, C, D and D' fragments with *defined structures* and *defined linkage sites*, does not reasonably provide enablement for compounds containing **any** A, B, C, D and D' fragments that are linked in **any** way. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is clear from applicant's specification how one might practice this invention with *specific* A, B, C, D and D' fragments having *defined linkage sites* and *defined structure*; however, there is insufficient guidance as to how to make/use compounds comprising **any** A, B, C, D and D' fragments that are linked in **any** way. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and

- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: Applicant's claims are directed to compounds "comprising structures of the formulae II - III" where these formulae are defined as "A-B-D-C-D'- (Formula (II))" and "A-B-D- and -D'-C (Formula (III))". For claims 12, 13, 15 and 16, the following applies:

- (1) no specific linkage sites between each of the moieties are depicted whatsoever and (2) several portions of this molecule are set forth in only functional terms.

Such represents very broad scope.

- (3 and 5) The state of the prior art and the level of predictability in the art:

Fluorescent conjugate compounds were well known at the time of filing; however, only limited numbers of such compounds were known and the specification gives no guidance to permit one of skill in the art to devise strategies for synthesis of *any* compound of formula (II - III) defined as "A-B-D-C-D'- (Formula (II))" and "A-B-D- and -D'-C (Formula (III))" that might have this function. The structures of possible variants are sufficiently diverse and one of ordinary skill would not be able to predict their structures. The limitation that the compounds comprise several linked fragments adds to the unpredictability because each portion of various structure would require completely different linkage strategies.

Moreover, portions of the claimed compounds that are defined functionally could have a wide variety of structures with various sites that would be possible for linkage. One of ordinary skill could not guess, *a priori*, how to make and use **any**

such compounds as one could not necessarily predict the linkage site and structure in the absence of any guidance without undue experimentation. Applicant's claimed scope of compounds represents only an invitation to experiment regarding possible fragments (A, B, C, D and D') with undefined structure and linkage sites.

(4) The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. Such persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have only provided examples of very specific compounds that comprise structurally defined fragments linked in a defined way. No generic strategy for determining the structure of each of the fragments and linkage sites is given. Specifically, the instant specification fails to identify that structure which is required for the claimed activity. The teachings of the instant specification coupled with the examples only support specific compounds that are made up of fragments of *defined structure* linked at *defined linkage sites*.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the full scope of the claimed compounds. Note that there must be sufficient

disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Response to Arguments

12. Applicant's arguments filed September 9, 2002 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

13. Applicant argues that the claims are enabled and points to portions of the instant specification and to the art for support (Response, pages 8-9). The examiner's position is that the definitions in the specification for the terms discussed in the rejection are *very broad*. As stated in the rejection, no limitations on the specific structure (i.e. specific structure of all elements and linkage between elements) are given and, as such, this could read on a wide variety of structures. The invention is such that each of the components must be present in operable form for successful practice of the invention. For example, each element must be able to be linked to the others and must retain the desired activity.

Most importantly, *the instant specification fails to identify that structure which is required for the claimed activity.*

14. Applicant argues that the linkages would be evident to one of ordinary skill. The examiner respectfully disagrees. As stated in the rejection, this is an unpredictable area of the art. The “predictability or lack thereof” in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art.

15. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved. See *In re Fisher*, 57 CCPA 1099, 427 F.2d 833, 839, 166 USPQ 18,24 (1970). Additionally, the Board has held on the issue of unpredictability that “... the unpredictability of an art area alone may be enough to create a reasonable doubt as to the accuracy of statements in the specification.” *Ex parte Singh*, 17 U.S.P.Q.2d 1714, 1716 (B.P.A.I. 1990).

16. See MPEP 716.09: Once the examiner has established a prima facie case of lack of enablement, the burden falls on the applicant to present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would have been able to make and use the claimed invention using the disclosure as a guide. *In re Brandstadter*, 484 F.2d 1395, 179 USPQ 286 (CCPA 1973). Applicant points to the 17 examples in the instant specification as being enabling for the full scope of the claims. However, the examiner maintains that the instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the full scope of the claimed compounds. For these reasons the above rejection of newly added claims 12, 13, 15 and 16 under 35 U.S.C. 112, first paragraph is made.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. First, claim 12 (and all claims dependent thereon) recite compounds "comprising structures of the formulae II - III" where these formulae are defined as "A-B-D-C-D' - (Formula (II))" and "A-B-D- and -D' -C (Formula (III))". This alternative

expression is confusing. See MPEP 2173.05(h): Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation, then "wherein R is A, B, C or D" shall also be considered proper.

B. The "open-ended" recitations in claim 12 are also confusing. The examiner is referring to the emphasized portions of the following formulae: "A-B-D-C-**D'**- (Formula (II))" and "A-B-**D-** and -**D'**-C (Formula (III))". It is simply unclear what is meant by the open-ended nature of these formulae.

C. Also, claim 12 contains a trademark ("Tentagel") in the claim. See MPEP 2173.05(u):

If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

D. Additionally, claim 12 recites the limitations "functionalized surfaces" and "materials grafted with functionalized surfaces", these are relative terms which

render the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. That is, how functionalized are the surfaces, and with what?

- E. Claim 13 recites the term “based” (i.e. “allyl based linkers”); this is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See also MPEP 2173.05(b). The addition of the word “based” extends the scope of the expression so as to render it indefinite.
- F. Claim 14 fails to further limit claim 12, on which it depends. This renders the claim indefinite. Specifically, the structures recited in claim 14 do not appear to fall within the limitations of claim 12. This is because the structures in claim 14 have E portions therein. Thus the compounds do not fall within the “structures of the formulae II - III” where these formulae are defined as “A-B-D-C-D’- (Formula (II))” and “A-B-D- and -D’-C (Formula (III))”.
- G. Claims 12, 13, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the specific structures and linkage sites for each of the moieties.

Thus, one of ordinary skill would not know the metes and bounds of the claimed invention. See also rejections under 112, first paragraph above.

Response to Arguments

19. Applicant's arguments filed September 9, 2002 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

20. Applicant argues that the claims are definite and states that one of ordinary skill would be able to ascertain the meaning of the claims. However, the examiner maintains the claims are indefinite for the reasons set forth in the rejections above. Note the following from MPEP 2173.02: If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973).

21. Also, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also, applicant is directed to MPEP 2173.05(a): [t]he meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed.

Status of Claims/Conclusion

22. No claims are allowed.


23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
April 28, 2003



MAURIE GARCIA BAKER PH.D.
PRIMARY EXAMINER